STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Viekira Pak® (ombitasvir/paritaprevir/ritonavir + dasabuvir)

Prior Authorization Request Form
Prior Authorization Continuation Request Form

Viekira Pak with or without ribavirin is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis. The product includes ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor (used as a booster), and dasabuvir, a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor.

Criteria for Approval

1) Patient must be diagnosed with Hepatitis C Genotype 1; **AND**

2) Viekira Pak must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**

3) Patient must have a documented diagnosis of **compensated cirrhosis** or a **fibrosis level of F3 or greater** (see below under Diagnostic/Disease Severity Evidence); **AND**

4) Patient must be eighteen (18) years of age or older; **AND**

5) Patient must be vaccinated against Hepatitis A and Hepatitis B; **AND**

6) Documented failure or contraindication to a preferred HCV therapy; **AND**

7) Patient has abstained from the use of illicit drugs and alcohol for a minimum of six (6) months, as indicated by the patient's signature on the Patient Consent form; **AND**

8) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success.

Duration of Approval

- Initial approval is for 6 weeks. All indications require submission of an HCV RNA level at the start of therapy and at treatment week 4 (TW4).

- Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**

Table 1. FDA Approved Regimens and Treatment Duration for Treatment Naïve or Interferon Experienced Patients**

Diagnosis	Approved Regimen	Duration
Genotype 1a – without cirrhosis	Viekira Pak™ + ribavirin	12 weeks
Genotype 1a – with compensated cirrhosis	Viekira Pak™ + ribavirin	12 or 24 weeks*
Genotype 1b – without cirrhosis	Viekira Pak™	12 weeks
Genotype 1b – with compensated cirrhosis	Viekira Pak™ + ribavirin	12 weeks
HCV/HIV-1 Co-Infection	Appropriate monotherapy listed above	12 or 24 weeks
(Post) Transplant Patients	Viekira Pak™	24 weeks

***Null Responders who have previously been treated with another HCV regimen shall be eligible for 24 weeks of coverage.**

****REGIMENS NOT LISTED ABOVE WILL BE CONSIDERED ON A CASE BY CASE BASIS WITH SUPPORTING DOCUMENTATION**

Diagnostic/Disease Severity Evidence (must be attached to request)

1) Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
   a. Cirrhotic features on imaging
   b. Ascites
   c. Esophageal varices
   d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)

2) Fibrosis level must be substantiated via biopsy or other accepted method (e.g. FibroSure Assay)

Criteria for Denial

1) Prescription for any other HCV anti-viral medication.

2) Prescriber has determined that the patient has not abstained from the use of illicit drugs and/or alcohol for at least six (6) months prior to the start of treatment.

3) Diagnosis for any genotype other than GT 1.

4) Patient has been previously treated with Viekira Pak.

5) Patient has not received a preferred regimen of HCV therapy or has no contra-indication to a preferred regimen.

6) Patient has decompensated cirrhosis (defined as a Child-Pugh score greater than 6 [class B or C]).

7) Patient is on dialysis.

8) Patient is taking a concomitant medication that has a significant clinical interaction with Viekira Pak (as indicated in the manufacturer's package insert).

9) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

Additional Considerations

1) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.

2) Lost or stolen medication replacement request will not be authorized.

References

1) Viekira Pak™ [package insert]. Abbvie, Revised 2/2015
2) AASLD 2015 Recommendations for Testing, Managing and Treating Hepatitis C (http://www.hcvguidelines.org)

Version 4 – DUR Board reviewed and approved with changes (02-25-2015)
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